UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,250	09/19/2005	Roberto Tonani	17758 (PC27531A)	6204

7590 11/21/2007

Peter I Bernstein
Scully Scott Murphy & Presser
Suite 300
400 Garden City Plaza
Garden City, NY 11530

EXAMINER	
BARKER, MICHAEL P	
ART UNIT	**PAPER NUMBER**
1626	

MAIL DATE	DELIVERY MODE
11/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,250	TONANI ET AL.	
	Examiner	Art Unit	
	Michael P. Barker	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 JAN 07, Preliminary Amendment*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-13 and 16* is/are rejected.

7)☒ Claim(s) *2-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

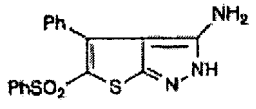
Claims 1-17 are pending in this Application.

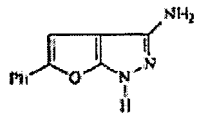
Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7 March 2005 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS was considered by the Examiner. Please refer to Applicant's copy of PTO-1449, submitted herewith.

Claim Rejections – 102(b)

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- **Claims 1** and **6** are rejected under 35 U.S.C. 102(b) as being anticipated by Sherif, et al. "Synthesis with heterocyclic B-enamino nitriles. An expeditious synthetic approach to polyfunctionally substituted 5-phenyl-sulfonylthiophenes and their fused derivatives", Monatshefte fuer Chemie (1997), 128 (6/7), pp. 687-96. Sherif, et al. discloses the following compound at p. 690: 

- **Claims 1** and **6** are rejected under 35 U.S.C. 102(b) as being anticipated by Elnagdi, et al. "The reaction of phenacylmalononitrile with hydrazines; synthesis of new pyridazinones", Gazzetta Chimica Italiana (1997), 127(12), pp. 791-94. Elnagdi, et al. disclose the following comopund at p. 792, No. 15: 

Please note, the International Search Report cites Examples 8a and 8b from Harb, et al. (cited in IDS) as grounds for an "X reference". However, it is unclear as to which compounds 8a and 8b refer. Therefore, no rejection is made using Harb, et al.

Claim Rejections – 102(e)

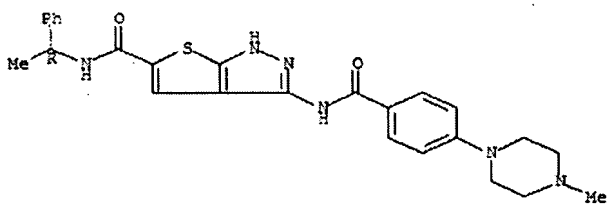
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3 and **6** are rejected under 35 U.S.C. 102(e) as being anticipated by WIPO Publication No. WO 2004/007504 A1, published 22 January 2004, claiming priority to U.S. Provisional Application No. 60/396,174, filed 17 July 2002. The '504 publication discloses the following compound:

RN 642412-09-3 CAPLUS
CN 1H-Thieno[2,3-c]pyrazole-5-carboxamide, 3-[[4-(4-methyl-1-piperazinyl)benzoyl]amino]-N-[(1R)-1-phenylethyl]- (CA INDEX NAME)

Absolute stereochemistry.



The applied reference has a common assignee and four common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected as it recites the limitation "as defined in example 6." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections – Obviousness Double Patenting (ODP)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and **6** are provisionally rejected over copending Application No. 11/050,360.

- Copending Application No. 11/050,360: **Claims 1-3** and **6** are anticipated by at least compound no. 1 of **Claim 19** of the '360 Application.

Claim Rejections - 35 USC § 112/101

Claims 7 and **13** provide for the "use of a compound of formula (I). . .", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7 and **13** are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112 ¶1

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Therefore, the Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'."

In re Wands, 8 USPQ2d 1400 (1988), discusses the following factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph:

1. ***The nature of the invention;***
2. ***The state of the prior art;***
3. ***The predictability or lack thereof in the art;***
4. ***The amount of direction or guidance present;***
5. ***The presence or absence of working examples;***
6. ***The breadth of the claims;***
7. ***The quantity of experimentation needed; and***
8. ***The level of skill in the art***

The nature of the invention

Claim 8 is drawn to methods of treating every disease caused by and/or associated with an altered protein kinase activity. **Claims 9-12** narrow the scope of **Claim 8** by specifying certain disease associated with or caused by altered protein kinase activity.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art, namely pharmacology, involves screening *in vitro* and *in vivo* to determine if the compounds exhibit desired pharmacological activities, which are then tested for their efficacy on human beings. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instantly claimed invention is unpredictable in terms of the subject matter of **Claims 8-12**.

As stated, pharmacology is an unpredictable art, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly complex, and one skilled in the art may recognize the claimed compounds as capable of inhibiting certain protein kinases (either directly or peripherally within the mechanism of action) in assays. However, such properties do not mean that the same group of compounds and compositions may treat the diseases in **Claims 8-12**.

The state of the prior art acknowledges the use of certain protein kinase inhibitors in the clinic or in clinical trials. (Noble, et al. Science, Mar. 19, 2004, vol. 303, pp. 1800-5). However, there is no literature supporting the notion that Applicant's claimed compounds or any protein kinase inhibitors are capable of treating each and every of the diseases listed in **Claims 8-12**.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance presented which substantiates Applicant's claimed compounds as capable of treating the diseases/disorders listed in **Claims 8-12**. The direction or guidance present in Applicant's Specification provides evidence that establishes the claimed compounds as capable of inhibiting certain protein kinases *in vitro*. No correlative *in vivo* data has been provided to support the scope of the instant claims.

The breadth of the claims, quantity of experimentation, and level of skill in the art

Claims 8-12 encompass the treatment of every disease associated with or caused by altered protein kinase activity. In order to treat a disease, one would need to demonstrate what the subject population is, what the necessary dose is for efficacy, and that the subject has recovered from such a disease. Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding **Claim 16**, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Objections

Claims 2-13: Dependent on a rejected base claim.

Claim 14: Refers to "formula (I)" without reference to **Claim 1**.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system,

see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

REBECCA ANDERSON
PRIMARY EXAMINER

Michael P. Barker
Patent Examiner, AU 1626
Technology Center 1600

(for) Joseph McKane
Supervisory Patent Examiner, AU 1626
Technology Center 1600